

REMARKS

Reconsideration of the present application in view of the above amendments and following remarks is respectfully requested. Claims 1-6, 8, 9, 11-57, 66-83, 134-182, 201-208, 220-222, 230-232, 239-242, 247-253, 255-258, 262-266, 271, 273-275, 278-281, 286, 288-291, 294, 298, 300-303, 309, 311-313, 321-323, 328, 330, 331, 336, 338-341, 346-348, 353-375 were pending. As noted above, Applicants have hereby cancelled claims 2, 43-56, 134-181 and 355-357 without prejudice to the filing of any divisional, continuation, or continuation-in-part application hereto, and which is to merely expedite allowance of the subject application. No new matter has been added. Therefore, claims 1, 3-6, 8, 9, 11-42, 57, 66-83, 182, 201-208, 220-222, 230-232, 239-242, 247-253, 255-258, 262-266, 271, 273-275, 278-281, 286, 288-291, 294, 298, 300-303, 309, 311-313, 321-323, 328, 330, 331, 336, 338-341, 346-348, 353, 354, and 358-375 are currently pending.

REJECTIONS UNDER 35 U.S.C. § 103(a)

(1) In the Office Action dated March 9, 2004, claims 1, 5, 8, 11, 15, 18-20, 57, 66-77, 182, 201, 208, 220-222, 230, 358-365, 373 and 374 were rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,080,099 (Slater *et al.*) in view of U.S. Patent No. 5,651,986 (Brem *et al.*). More specifically, it is alleged that it would have been obvious for a person having ordinary skill in the art to modify the system and method of Slater *et al.* to include the use of a biodegradable polymer with a cell-cycle inhibitor as taught by Brem *et al.* to arrive at the instant invention because such a spacer would provide a means of supplying localized chemotherapy and localized radiation at a tumor site.

Applicants respectfully traverse this ground of rejection and submit that Slater *et al.* and Brem *et al.*, taken alone or in combination, fail to teach or suggest the claimed invention. The present invention is directed, in pertinent part, to a therapeutic device comprising a device, which locally administers radiation, and a spacer, wherein the spacer includes a polymer and a cell-cycle inhibitor. As previously made of record and as conceded in the instant Office Action (at page 4, bottom paragraph through page 5, first paragraph, Paper No. 16), Slater *et al.* fail to

teach or suggest a spacer that comprises a polymer, much less a spacer that includes a polymer and a cell-cycle inhibitor. Applicants agree that Slater *et al.* describe a radioactive seed that consists of a capsule containing a radioactive isotope, and describe linking of such seeds together with a "bioabsorbable spacer." However, even assuming, *arguendo*, that a person having ordinary skill in the art would know that a "bioabsorbable spacer" could be a polymer, Slater *et al.* are silent with regard to what material could be used as a "bioabsorbable spacer" and are silent as to how to make such a spacer. Therefore, Slater *et al.* fail to teach or suggest a therapeutic device according to the instant invention.

Furthermore, the addition of Brem *et al.* does not remedy the deficiencies of Slater *et al.* Applicants agree that Brem *et al.* disclose the use of polymer compositions containing chemotherapeutic agents to treat cancer, while Slater *et al.* disclose the use of radiation therapy to treat cancer. However, Brem *et al.* fail to teach or suggest the use of a device that locally administers radiation, much less a device that locally administers radiation in combination with a spacer that includes a cell-cycle inhibitor. Furthermore, Brem *et al.* do not teach or suggest a therapeutic device or a device having a polymer as a spacer. Hence, Slater *et al.* and Brem *et al.*, taken alone or in combination, fail to teach or suggest a device that combines radiation and a cell-cycle inhibitor according to the instant invention.

Applicants respectfully submit that where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under §103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991). Furthermore, the mere fact that the teachings of the prior art *can* be combined or modified, or that a person having ordinary skill in the art is *capable* of combining or modifying the teachings of the prior art, does not make the resultant combination *prima facie* obvious, as the prior art must also suggest the desirability of the combination (*see, e.g., In re Mills*, 16 U.S.P.Q.2d 1430, Fed. Cir. 1990; *In re Fritch*, 23 U.S.P.Q.2d 1780, Fed. Cir. 1992).

Applicants also submit that when prior art references require a selective combination to render obvious a subsequent invention, there must be some reason for the combination *other* than the hindsight gleaned from the invention itself. To this end, reasons must be provided in the Office Action to show that a person having ordinary skill in the art, confronted with the same problems as the instant inventors and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. *See In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998). In addition, when relying on the skill in the art, there must be provided an explanation of what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination. *Id.* Here, the Examiner invokes the skill in the art, but fails to provide a cogent explanation as to how or why a person having ordinary skill in the art could arrive at the claimed methods in view of the cited references. As the Federal Circuit has noted, if merely "a rote invocation [of the skill in the art] could suffice to supply motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technical advance." *Id.*

In sum, Applicants respectfully submit that a *prima facie* case of obviousness has not been set forth in the Office Action. In particular, no evidence has been provided that, at the time of filing the instant application, a person having ordinary skill in the art would have been motivated to arrive at the claimed invention given the disclosures of the cited references. Accordingly, Applicants respectfully submit that the instant claims satisfy the requirements of 35 U.S.C. § 103(a) and, therefore, request that this rejection be withdrawn.

(2) In the Office Action, claims 9, 11 and 83 were rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,080,099 (Slater *et al.*) and U.S. Patent No. 5,651,986 (Brem *et al.*) in view of U.S. Patent No. 6,248,057 (Mavity *et al.*). In particular, it is alleged that it would have been obvious for a person having ordinary skill in the art to modify the device and method of Slater *et al.* and Brem *et al.* to include the use of a coating on the radioactive seed for delivering the cell-cycle inhibitor, as taught by Mavity *et al.*, to provide a means of delivering radiation and a chemotherapeutic agent to the same spot rather than have a chemotherapeutic agent adjacent to a radioactive seed.

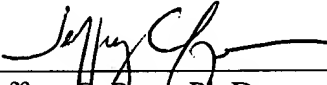
Applicants respectfully traverse this ground of rejection and submit that Slater *et al.*, Brem *et al.* and Mavity *et al.*, taken alone or in combination, fail to teach or suggest the claimed invention. As set forth above, Slater *et al.* and Brem *et al.* fail to teach or suggest the instant invention, particularly a spacer comprised of a polymer and a cell-cycle inhibitor. The addition of Mavity *et al.* does not remedy the deficiencies of Slater *et al.* and Brem *et al.* That is, Mavity *et al.*, while disclosing a polymer consisting of a chemotherapeutic drug and coated with a radiation source, fail to teach or suggest (and in fact teach away from) a spacer or a spacer comprising a polymer and a cell-cycle inhibitor. In addition, Applicants respectfully submit that claims 9 and 11 are not so limited as to have the radiation source and cell cycle inhibitor present only in the spacer. For example, a device that locally administers radiation can be composed of a polymer that releases the source of radiation, while the spacer comprises a polymer with a cell-cycle inhibitor. As noted above, Applicants respectfully submit that the mere fact that the teachings of the prior art *can* be combined or modified does not make the resultant combination *prima facie* obvious. In short, the cited references, taken alone or in combination, fail to teach or suggest a therapeutic device that locally administers radiation having a spacer comprised of a polymer and a cell-cycle inhibitor.

Accordingly, Applicants respectfully submit that the present invention satisfies the requirements of 35 U.S.C. § 103(a) and, therefore, request that these rejections be withdrawn.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the pending claims in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. The Examiner is urged to contact the undersigned attorney if there are any questions prior to allowance of this matter.

Respectfully submitted,
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